Our STN: BL 125518/528

**SUPPLEMENT APPROVAL**
June 30, 2022

BioVex, Inc., a wholly owned subsidiary of Amgen, Inc.
Attention: Stephanie Hansen
Manager, Regulatory Affairs
One Amgen Center Drive, Mail Stop 27-2-D
Thousand Oaks, CA 91320

Dear Ms. Hansen:

Please refer to your supplement to your Biologics License Application (BLA) received December 13, 2021, submitted under section 351(a) of the Public Health Service Act (PHS Act) for Talimogene laherparepvec (IMLYGIC).

We also refer to our supplement approval letter dated June 14, 2022, which contained the following error:

> The revision dates were not included in the final versions submitted under amendment 1, dated May 16, 2022, and Medication Guide submitted under original supplement, dated December 13, 2021

This replacement approval letter incorporates the correction of the error. The effective approval date will remain June 14, 2022, the date of the original supplement approval letter.

We have approved your request received December 13, 2021, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Talimogene laherparepvec (IMLYGIC), to add the risk of hepatic hemorrhage with transcutaneous intrahepatic route of administration to the Warnings & Precautions section of the IMLYGIC U.S. Prescribing Information, and to update the Medication Guide to align with 21 CFR 208.20(b)(8)(i).

**LABELING**

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling Package Insert and Medication Guide submitted under amendment 2, dated June 28, 2022.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert and Medication Guide submitted on June 28, 2022. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125518, at the time of use and include implementation information on Form FDA 356h.

**ADVERTISING AND PROMOTIONAL LABELING**

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research